

US EPA ARCHIVE DOCUMENT

## **Factual Statements: EPA's Authority and Statutory Considerations**

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To explore approaches to making factual statements on pesticide labels, it is important to understand the legal structure that provides EPA with authority in this area. It also is important to understand other regulatory programs that govern the content of labels and advertising more generally. With respect to EPA's authority, FIFRA is the starting point in such an analysis. It authorizes EPA to regulate and approve pesticide labels and establishes the parameters within which EPA must operate.

In the hierarchy of authority under FIFRA, EPA's regulations are authoritative and binding on both the Agency and the regulated community. They are authorized by FIFRA and can only be issued after a notice and comment procedure. Regulations can be challenged in court on grounds that they exceed the Agency's statutory authority or are arbitrary, capricious or an abuse of discretion. These arguments generally are based on the record compiled during the rulemaking process.

EPA also can issue Guidelines and internal guidance. These types of documents are not binding on the Agency or the regulated community. They typically represent a general Agency view on a particular issue. However, they are not binding on either the Agency or the regulated community. The Label Review Manual is an example of this type of EPA guidance. .

**FIFRA.** The Federal Insecticide, Fungicide and Rodenticide Act, (FIFRA), 7 USC §136 *et seq.* authorizes EPA to approve pesticide labels and sets forth certain requirements for the content of labels. Provisions affecting registrants' ability to include factual statements on labels appear in a number of places in the statutes. Among the most important are the following:

- The definition of misbranded in 7 USC § 136(q). This section states that a pesticide is misbranded, if "its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular."
- The registration provisions, which appear in 7 USC § 136a, which provide, in part, that for antimicrobial pesticides, it "shall not be a violation of this chapter for a registrant to modify the labeling . . . to include relevant information on product efficacy, product composition, container composition or design or other characteristics that do not relate to any pesticidal claim or pesticidal activity." This provision goes on to state that such statements "shall not be false or misleading or detract from" required statements, and establishes a procedure for EPA to be notified of such language with an opportunity for disapproval.
- The unlawful acts section, which includes as an unlawful act, to "distribute or sell" a pesticide which is "misbranded." 7 USC §136j.

**EPA Regulations.** FIFRA authorizes EPA to issue regulations to implement the pesticide registration program. The Agency has issued voluminous regulations addressing a wide range of issues. With respect to factual statements on labels, the most significant provision appears to be, 40 C.F.R. § 156.10. This section provides that a pesticide will be deemed misbranded by EPA if its labeling is “false or misleading.” The regulation provides the following example of such statements:

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) “Contains all natural ingredients”;

(B) “Among the least toxic chemicals known”

(C) “Pollution approved”

**Label Review Manual.** EPA also has relied upon the statutory definition of misbranded in drafting provisions of the Label Review Manual (LRM). The LRM is a “training tool” for OPP personnel and “guidance for product management team members who are responsible for performing label reviews.” LRM, Ch. 1. It is not binding on the Agency or the regulated community. Chapter 12 of the LRM generally addresses EPA’s views on misbranding. It provides guidance to staff not to approve “false and misleading” statements, and states that labels should not be approved if they include a claim such as “natural,” or “biodegradable” except as to packaging under certain circumstances. The LRM goes well beyond the statute or regulations in the level of specificity it provides. It is important to recognize, however, that it is only internal guidance. It does not have the force of law and can be modified at any time by EPA without going through any required process.

Viewed against this background, EPA’s authority to control factual statements on pesticide labels must be viewed as constrained by its basic authority is to prohibit false and misleading statements. With respect to antimicrobial pesticides this authority is further constrained by section 136a (c) (9), which allows registrants to make statements that do not relate to a pesticidal claim, and provides EPA with authority to disapprove such statements only if they interfere with required label text.

**FTC Regulation of Claims.** Beyond EPA’s authority to regulate label statements, statements on pesticide labels are subject to the same broad requirements as all products. This includes the FTC’s Guidelines on Environmental Claims, which appear at 16 CFR Part 260, and its general authority under section 5 of the Federal Trade Commission Act, to act against false or misleading claims. The FTC’s Advertising Substantiation Guidelines require a “reasonable basis consist[ing] of competent and reliable evidence,” to support any claim on labeling or in advertising. *See* Policy Statement on the Advertising Substantiation Doctrine. 49 Fed. Reg. 30999 (1984). The Commission’s Guidelines on Environmental Marketing Claims apply these principles to environmental claims. They require, for example, qualification if a claim relates only to a portion of a

product (e.g. packaging) rather than the entire product. 16 CFR §260.6. The FTC Guidelines provide a framework for ensuring claims on pesticide labels that are not regulated by EPA are truthful and not misleading. They are not regulations, but rather represent the FTC's interpretation of its statute. Companies operating outside of FIFRA have infrastructure in place to ensure compliance with these important controls on advertising and labels.